

SECTION B:

SUMMARY OF SCIENTIFIC DATA*

***To the best of the petitioners' knowledge, all non-clinical laboratory studies evaluated as part of this petition were conducted in compliance with the good laboratory practice regulations as set forth in 21 C.F.R. Part 58. To the best of the petitioners' knowledge, all clinical or other human investigations evaluated as part of this petition were either conducted in compliance with the requirements for institutional review as set forth in 21 C.F.R. Part 56 or were not subject to such requirements in accordance with 21 C.F.R § 56.104 or 21 C.F.R. § 56.105. To the best of the petitioners' knowledge, all clinical or other human investigations were conducted in compliance with the requirements for informed consent as set forth in 21 C.F.R. Part 50.**